



3763

0360

Patent
Attorney's Docket No. 032005-124

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Mark Ashby, et al.

Application No.: 10/007,204

Filed: November 8, 2001

For: SYSTEM AND METHOD FOR
DELIVERING HEMOSTASIS
PROMOTING MATERIAL TO A
BLOOD VESSEL PUNCTURE SITE BY
FLUID PRESSURE

Group Art Unit: Unassigned

Examiner: Unassigned

RECEIVED
APR - 3 2002
TECHNOLOGY CENTER R3700

#5

INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☒ [x] No additional fee for submission of an IDS is required.
- ☐ [] The fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ [] A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ [] A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ [] Charge \$_____ to Deposit Account No. 02-4800 for the fee due.
- ☐ [] A check in the amount of \$_____ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

By: David Heckadon
David Heckadon
Registration No. 50,184

Date:



Patent
Attorney's Docket No. 032005-124

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)

Mark Ashby et al)

Application No.: 10/007,204)

Filed: November 8, 2001)

For: SYSTEM AND METHOD FOR)
DELIVERING HEMOSTASIS)
PROMOTING MATERIAL TO A)
BLOOD VESSEL PUNCTURE SITE BY)
FLUID PRESSURE)

Group Art Unit: Unassigned

Examiner: Unassigned

RECEIVED

APR - 3 2002

TECHNOLOGY CENTER R3700

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

U.S. Documents

| | | | |
|----|-----------|------------|---------|
| 1. | 581,235 | Kenyon | 4/1897 |
| 2. | 1,578,517 | Hein | 3/1926 |
| 3. | 2,086,580 | Shirley | 7/1937 |
| 4. | 2,465,357 | Correll | 3/1949 |
| 5. | 2,492,458 | Bering | 12/1949 |
| 6. | 2,507,244 | Correll | 5/1950 |
| 7. | 2,558,395 | Studer | 6/1951 |
| 8. | 2,597,011 | MacMasters | 5/1952 |

| | | | |
|-----|-----------|--------------------|---------|
| 9. | 2,680,442 | Linzmayer | 6/1954 |
| 10. | 2,761,446 | Reed | 9/1956 |
| 11. | 2,814,294 | Figge | 11/1957 |
| 12. | 2,824,092 | Thompson | 2/1959 |
| 13. | 2,899,362 | Sieger, Jr. et al. | 8/1958 |
| 14. | 3,157,524 | Artandi | 11/64 |
| 15. | 3,724,465 | Duchane | |
| 16. | 4,000,741 | Binard | 1/77 |
| 17. | 4,323,072 | Rosenbluth et al. | 4/82 |
| 18. | 4,340,066 | Shah | 7/82 |
| 19. | 4,390,018 | Zulowski | 6/83 |
| 20. | 4,515,637 | Cioca | 5/85 |
| 21. | 4,587,969 | Gillis | 5/86 |
| 22. | 4,588,395 | Lemelson | 5/86 |
| 23. | 4,619,261 | Guerriero | 10/86 |
| 24. | 4,619,913 | Luck et al. | 10/86 |
| 25. | 4,645,488 | Matukas | 2/87 |
| 26. | 4,744,364 | Kensey | 8/89 |
| 27. | 4,790,819 | Li et al. | 12/88 |
| 28. | 4,829,994 | Kurth | 5/89 |
| 29. | 4,850,960 | Grayzel | 7/89 |
| 30. | 4,852,568 | Kensey | 8/89 |
| 31. | 4,890,612 | Kensey | 1/90 |
| 32. | 4,900,303 | Lemelson | 2/90 |
| 33. | 4,292,246 | Sinofsky | 5/90 |
| 34. | 4,936,835 | Haaga | 6/90 |
| 35. | 4,950,234 | Fujioka et al. | 8/90 |
| 36. | 5,007,895 | Burnett | 4/91 |
| 37. | 5,021,059 | Kensey et al. | 6/91 |

| | | | |
|-----|-----------|---------------|-------|
| 38. | 5,053,046 | Janese | 10/91 |
| 39. | 5,061,274 | Kensey | 10/91 |
| 40. | 5,080,655 | Haaga | 1/92 |
| 41. | 5,108,421 | Fowler | 4/92 |
| 42. | 5,163,904 | Lampropoulous | 11/92 |
| 43. | 5,167,624 | Butler et al. | 12/92 |
| 44. | 5,192,300 | Fowler | 3/93 |
| 45. | 5,192,301 | Kamiya et al. | 3/93 |
| 46. | 5,195,988 | Haaga | 3/93 |
| 47. | 5,220,926 | Jones | 6/93 |
| 48. | 5,221,259 | Weldon et al. | 6/93 |
| 49. | 5,275,616 | Fowler | 1/94 |
| 50. | 5,310,407 | Casale | 5/94 |
| 51. | 5,322,515 | Karas et al. | 6/94 |
| 52. | 5,325,857 | Nabai et al. | 7/94 |
| 53. | 5,334,216 | Vidal et al. | 8/94 |
| 54. | 5,366,480 | Corriveau | 11/94 |
| 55. | 5,370,656 | Shevel | 12/94 |
| 56. | 5,383,896 | Gershony | 1/95 |
| 57. | 5,383,899 | Hammerslag | 1/95 |
| 58. | 5,385,550 | Su et al. | 1/95 |
| 59. | 5,388,588 | Nabai et al. | 2/95 |
| 60. | 5,391,183 | Janzen et al. | 2/95 |
| 61. | 5,419,765 | Weldon | 5/95 |
| 62. | 5,431,639 | Shaw | 7/95 |
| 63. | 5,437,631 | Janzen | 8/95 |
| 64. | 5,467,780 | Nabai | 11/95 |
| 65. | 5,478,352 | Fowler | 12/95 |
| 66. | 5,479,936 | Nabai | 1/96 |

| | | | |
|-----|-----------|------------|-------|
| 67. | 5,486,195 | Myers | 1/96 |
| 68. | 5,522,850 | Yomtov | 6/96 |
| 69. | 5,526,822 | Burbank | 6/96 |
| 70. | 5,529,577 | Hammerslag | 6/96 |
| 71. | 5,540,715 | Katsoros | 7/96 |
| 72. | 5,542,914 | Van Iten | |
| 73. | 5,545,178 | Kensey | 8/96 |
| 74. | 5,558,853 | Quay | 9/96 |
| 75. | 5,591,204 | Janzen | 1/97 |
| 76. | 5,591,205 | Fowler | 1/97 |
| 77. | 5,601,602 | Fowler | 2/97 |
| 78. | 5,645,566 | Brennenman | 7/97 |
| 79. | 5,653,730 | Hammerslag | 8/97 |
| 80. | 5,665,107 | Hammerslag | 9/97 |
| 81. | 5,649,547 | Ritchart | 7/97 |
| 82. | 5,681,279 | Roper | 10/97 |
| 83. | 5,716,375 | Fowler | 2/98 |
| 84. | 5,725,498 | Janzen | 3/98 |
| 85. | 5,741,223 | Janzen | 4/98 |
| 86. | 5,769,086 | Ritchart | 6/98 |
| 87. | 5,775,333 | Burbank | 7/98 |
| 88. | 5,800,389 | Burney | 9/98 |
| 89. | 5,810,806 | Ritchart | 9/98 |
| 90. | 5,830,130 | Janzen | 11/98 |
| 91. | 5,902,310 | Foerster | 5/99 |
| 92. | 5,858,008 | Capaccio | 1/99 |
| 93. | 6,027,471 | Fallon | 2/00 |
| 94. | 6,027,482 | Imbert | 2/00 |
| 95. | 6,071,301 | Cragg | 6/00 |

| | | | |
|------|-----------|---------|-------|
| 96. | 6,086,607 | Cragg | 7/00 |
| 97. | 6,161,034 | Burbank | 12/00 |
| 98. | 6,162,192 | Cragg | 12/00 |
| 99. | 6,183,497 | Sing | 2/01 |
| 100. | 6,315,753 | | 11/01 |

Foreign Patents

| | | | |
|------|------------|--------|-------|
| 101. | 1509023 | UK | 4/78 |
| 102. | 1569660 | UK | |
| 103. | 0032826 | EP | 7/81 |
| 104. | 0476178 | EP | 3/92 |
| 105. | 0482350 | EP | 4/92 |
| 106. | WO96/08208 | PCT | 3/96 |
| 107. | WO98/06346 | PCT | 2/98 |
| 108. | WO99/66834 | PCT | 12/99 |
| 109. | 2641692 | France | 7/90 |
| 110. | 782814 | Russia | 11/80 |
| 111. | 1088709A | Russia | 4/84 |

Articles

112. Allison, D., et al., "Per cutaneous liver biopsy and track embolization with steel coils", *Radiology*, Vol. 169, pp. 261-263, (1988)
113. Chuang, V., et al., "Sheath needle for liver biopsy in high-risk patience", *Radiology*, Vol. 166, pp. 261-262 (1988)
114. Fandrich, C., et al. "Small gauge gelfoam plug liver biopsy in high risk patients", *Australian Radiology*, Vol. 40, pp. 230-234 (1996).
115. Foran, JPM, et al., "Early mobilisation afer Per cutaneous cardiac catheterisation using collagen plug (Vasoseal) maemostatis", *BRHeart*, Vol. 69, pp. 424-429 (1993)

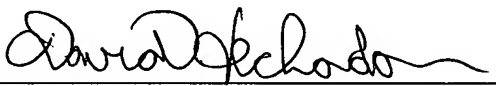
116. Gibbs, JSR, "Femoral arterial hemostasis", *J. Interventional Card*, Vol. 5, pp. 85-88, (1992).
117. Kiemeneiji, F, et al., "Improved anticoagulation management after Palmaz Schatz coronary stent implantation by sealing the arterial puncture site with vascular hemostasis device", *Catheterization and Cardiovascular Diagnosis*, Vol. 30, pp. 317-322 (1993).
118. Kussmaul, WG, "Rapid arterial hemostasis", *J. Am. Coll. Card.*, Vol. 25, pp. 1685 - 1692 (1995).
119. Pharmacia & Upjohn Manufacturer Brochure "Gelfoam Sterile Sponge, Sterile Powder and Sterile Film", pp 1-34 (May 1997)
120. Pharmacia & Upjohn Manufacturer Brochure, "Gelfoam Sterile Powder", (February 1996)
121. Pharmacia & Upjohn Manufacturer Brochure, "Gelfoam Sterile Powder", (March 1996)
122. Pharmacia & Upjohn Manufacturer Brochure, September 1996
123. Pharmacia & Upjohn Manufacturer Specification, "Gelfoam Sterile Sponge, Sterile Powder and Sterile Film" pp. 1-23 (November 1996)
124. Ricardo, D., et al., "Part 1. Embolotherapy: Agents, Equipment and Techniques", *Vascular Embolotherapy*, Vol. 4, pp. 29 and 33.
125. Riley, SA, "Per cutaneous liver biopsy with plugging of needle track: a safe method for use in patients with impaired coagulation", *The Lancet*, p. 436 (1964)
126. Sanborn, T., "Multicenter randomized trial comparing Per cutaneous collagen hemostasis device with conventional manual compression after diagnostic angiography and angioplasty", *J. Am. Coll. Card.*, Vol. 22, pp. 1273-1279, (1993)
127. Silber, S., "Rapid Hemostasis of arterial puncture sites with collagen in patients undergoing diagnostic interventional cardiac Catheterization", *Clinical Cardiology*, Vol. 20, pp. 981-992, (1997)
128. Smith, T., "Per cutaneous transhepatic live biopsy with tract embolization", *Radiology*, Vol. 198, pp. 769-774 (1996)
129. Zins, M., "US-guided Per cutaneous liver biopsy with plugging of the needle track", *Radiology*, Vol. 184, pp. 841-843, (1992)

The documents are being submitted within 3 months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later, therefore no fee or statement is required under 37 C.F.R. § 1.97(b).

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
David Heckadon
Registration No. 50,184

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: